

# Comparative study of operative treatment and percutaneous transluminal angioplasty/stenting for recurrent carotid disease

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**Purpose:** This study is a nonrandomized parallel comparison of the outcome for carotid endarterectomy (CEA) and percutaneous transluminal angioplasty (PTA)/stenting for recurrent carotid artery stenosis (RCS).

**Methods and Patients:** Between June 1996 and June 2000, 83 carotid procedures (58 reoperations, Group I, and 25 PTA/stentings, Group II) were done for RCS. Patients were followed at regular intervals with duplex ultrasound scanning. The outcome of the stented group (Group II) was divided into early experience (Group IIA, first 12 cases) and late experience (Group IIB, last 13 cases) for learning curve consideration, and each was compared with the reoperation group. A Kaplan-Meier life table analysis was used to estimate the stroke-free survival rates and freedom from  $\geq 50\%$  recurrent restenosis for both groups.

**Results:** The demographic and clinical characteristics and indications for intervention were similar for both groups. The mean time from the original CEA to reoperation was 41 months in Group I versus 43 months in Group II. Overall, stenting had higher 30-day stroke rates than reoperations—16% (3 major and 1 minor stroke) versus 3.4% (1 out of 2 [1.7%] was a major stroke,  $P < .05$ ). However, Group IIB had similar major stroke rates to Group I (0% versus 1.7%). Cranial nerve injury was noted in 10 patients (17%) in Group I (only 1 [1.7%] was permanent) versus 0% in Group II ( $P < .05$ ). Recurrent  $\geq 50\%$  restenosis was higher in Group II than in Group I (24% versus 0%,  $P < .001$ ). Stroke-free survival rates at 6 months and 1, 2, and 3 years for Group I were 97%, 97%, 94%, and 82%, respectively, versus 79%, 79%, 79%, and 79%, respectively, for Group II ( $P = .059$ ). Freedom from recurrent  $\geq 50\%$  restenosis rates at 6 months and 1, 2, and 3 years were 100%, 100%, 100%, and 100%, respectively, for Group I versus 100%, 94%, 65%, and 44%, respectively, for Group II ( $P < .0001$ ).

**Conclusions:** Carotid PTA/stenting has a similar 30-day stroke rate to that of reoperation for RCS once experience is established. However, PTA/stenting has a higher incidence of restenosis than reoperation, which is associated with a percentage of cranial nerve injuries. Therefore, PTA/stenting can be an alternative to reoperation, particularly in marginal surgical risk patients. (J Vasc Surg 2001;34:831-8.)

Carotid endarterectomy (CEA) is considered the surgical intervention of choice for symptomatic and asymptomatic carotid artery stenosis. This procedure has been performed with increasing frequency since the conclusion of the North American Symptomatic Carotid Endarterectomy trial and the Asymptomatic Carotid Atherosclerosis Study trial.<sup>1,2</sup> Reoperation for restenosis is much more controversial because of the more benign nature of these lesions, especially those occurring within 2 years of the CEA.<sup>3-7</sup>

Reoperation for significant carotid restenosis is generally indicated for patients with symptomatic disease.<sup>3-7</sup> Other authors also recommend reoperation for  $>80\%$  asymptomatic restenosis.<sup>8</sup>

The advent of percutaneous transluminal angioplasty (PTA)/stenting has prompted many investigators to advocate this as the procedure of choice for carotid restenosis because it is perceived that reoperation carries higher perioperative stroke rates and cranial nerve injury rates than primary CEA.<sup>9-13</sup>

This present study compares the early and late outcomes of reoperation and PTA/stenting for carotid restenosis. Only one previous study compares the operative and endovascular treatment of carotid restenosis from the same institution.<sup>13</sup>

## PATIENT POPULATION AND METHODS

All reoperations (Group I, 58 patients) and PTA/stenting (Group II, 25 arteries in 23 patients) for carotid restenosis that were performed during a recent 4-year period between June 1996 and June 2000 by one vascular surgeon (AFA) and one vascular medicine interventionalist (MB) at the same institution were analyzed. Patients who had PTA/stenting were considered by their surgeons to be too high-risk for conventional reoperation. These include 2 patients with previous neck irradiation, 5 with high cervical lesions (based on previous CEA findings), and 3 with past cranial nerve injuries (two vagal nerves and one hypoglossal nerve). In 13 other patients, the surgeons

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(general and cardiac surgeons with vascular privileges) felt that they were too morbid for reoperation. All patients underwent carotid color duplex ultrasound scan/magnetic resonance angiography and arteriography before reoperation. Preoperative risk factors were determined for each patient, along with the preoperative use of antiplatelet therapy. Indications for surgery were categorized into hemispheric transient ischemic attacks (TIAs), hemispheric strokes, amaurosis fugax, nonhemispheric TIAs, and asymptomatic carotid restenoses. All patients with reoperations were administered aspirin therapy (325 mg daily) if not contraindicated, within 24 hours after the operation. Patients who underwent PTA/stenting were administered aspirin therapy and ticlopidine (Ticlid, 250 mg twice daily) or clopidogrel bisulfate (Plavix, 300 mg, followed by 75 mg daily) for 30 days. Aspirin therapy was continued indefinitely as it was in patients with reoperations.

All reoperations were performed under general anesthesia with systemic heparin and routine shunting using a carotid Argyle shunt (C. R. Bard, Inc, Billerica, Mass). Polytetrafluoroethylene (Goretex) patch angioplasties alone were done on 36 arteries (early lesions,  $\leq 24$  months), and 22 other arteries (late lesions,  $\geq 24$  months) underwent re-endarterectomy with patch angioplasty in 20 cases, and two other lesions (25 and 26 months) had PTFE patch angioplasty alone. None of these patients had interpositional grafts.

The following were contraindications for reoperations or PTA/stenting: intracranial stenosis that exceeded the severity of the extracranial stenosis, severe disability from stroke, presence of severe aortoiliac or peripheral vascular disease that precluded vascular access for PTA/stenting, and inability to give informed consent.

**Carotid PTA and stenting protocol.** Aspirin (325 mg daily) and ticlopidine (Ticlid, 250 mg twice daily) or clopidogrel bisulfate (Plavix, 75 mg daily) were given for 7 days before the procedure and on the morning of the procedure. Preoperative sedation was avoided. Using local anesthesia with 1% xylocaine, the surgeon introduced a 5-French sheath into the common femoral artery by using the modified Seldinger technique. Through this sheath, a 5-French diagnostic catheter was used to selectively engage the innominate or carotid arteries for angiography after an oblique arch aortogram was performed. The catheter was navigated into the common carotid artery, allowing selective angiography of the vessel to be performed in orthogonal views, and 5000 units of heparin were administered intravenously. In the first six cases, 10,000 units of intravenous heparin were given, but because of one case of intracerebral hemorrhage during this time, the dosage was decreased to 5000 units. A guidewire was navigated into the external carotid artery, and the diagnostic catheter was advanced into the distal external carotid artery. A 0.038-inch exchange length support wire was placed in the external carotid artery, and the catheter was removed. A 9-French multipurpose catheter with a 7-French introducer was then inserted over the support wire and advanced into the area of interest using meticulous fluoroscopic guidance. The introducer and

support wire were removed, and the catheter was flushed using the retrograde flush technique. The target lesion was crossed with a soft-tipped 0.018-inch wire and dilated with a 4-mm balloon catheter. Finally, the stent was deployed in the internal carotid artery, which may extend into the common carotid artery, if needed. This was followed by post-stent balloon angioplasty in our early experience; however, postdilatation was avoided when possible during the last 2 years. The length and size of the stent were determined according to angiography. A completion angiogram, including digital subtraction intracranial angiography, was performed.

Post-stent anticoagulation was not used; however, all patients were continued on ticlopidine (Ticlid, 250 mg twice daily) or clopidogrel bisulfate (Plavix, 300 mg initial dose, followed by 75 mg daily) for 30 days, and aspirin was continued indefinitely.

Femoral venous access was gained in some patients, and a pacemaker was either placed on the right ventricle or made available for the treatment of a rare malignant bradycardia or asystole during the balloon inflation procedure.

All patients underwent placement of a single stent, except for one patient who had two stents. The type of stents used included Palmaz stent (J & J Interventional Systems, Warren, NJ) in the first two patients and Wall stent (Boston Scientific, Natick, Mass) or Smart stent (Cordis Endovascular, Warren, NJ) in the remaining patients.

**Surveillance protocol.** All patients underwent clinical follow-up, and every effort was made for these patients to have immediate postoperative color duplex ultrasound scanning, to be repeated at 30 days, 6 months, 12 months, and every year thereafter, with an ATL Ultramark 9 HDI system or HDI 3000 system (Advanced Technology Laboratory, Inc, Bellevue, Wash). Duplex scanning was used to detect the presence of recurrent restenosis after reoperation or carotid PTA/stenting.

Angiographic success after carotid PTA/stenting was defined as achieving  $<30\%$  residual stenosis. Neurologic complications were classified as one of the following: a TIA, which was defined as a new neurologic deficit that resolved completely within 24 hours; a minor stroke, a new neurologic deficit that either resolved completely within 7 days or increased the National Institutes of Health stroke scale score by three or less; or a major stroke, a new neurologic deficit that persisted after 7 days and increased the National Institutes of Health stroke scale score by four or more. If a patient had a neurologic deficit after PTA/stenting or reoperation, magnetic resonance imaging or computed tomography of the head was performed.

## STATISTICAL METHODS

The time to the occurrence of events (time to  $\geq 50\%$  recurrent restenosis, time to stroke or death) was calculated using the Kaplan-Meier method. Statistical comparisons were made with the Wilcoxon rank sum test. The statistical comparison of continuous data were examined with the unpaired Student *t* test, and discrete variables were compared with the  $\chi^2$  or Fisher exact test.

**Table I.** Demographic/clinical indications—reoperation versus PTA/stenting

	<i>Reoperation</i>	<i>PTA/stenting</i>	<i>P value</i>
No. of arteries (patients)	58 (58)	25 (23)	
Mean age (y) (range)	70 (48-81)	71 (46-82)	NS
Female sex	32 (53%)	12 (52%)	NS
Smoking	35 (60%)	15 (65%)	NS
Diabetes mellitus	13 (22%)	6 (29%)	NS
Hypertension	45 (78%)	19 (76%)	NS
Hypercholesterolemia	33 (57%)	14 (61%)	NS
Coronary artery disease	31 (53%)	13 (57%)	NS
Indications for procedure			
Symptomatic, TIA/stroke	46 (79%)	18 (72%)	NS
Asymptomatic	12 (21%)	7 (28%)	NS
Mean time from original CEA to reoperation (mo) (range)	41 (4-249)	43 (6-238)	NS
Mean time to follow up (mo) (SE)	22.1 (1.61)	18.1 (3.01)	NS

NS, Not significant.

**Table II.** 30-day perioperative and all neurologic complications

<i>Complication</i>	<i>Reoperation CEA</i>	<i>PTA/stenting</i>	<i>P value</i>
Number of arteries (patients)	58 (58)	25 (23)	
All ipsilateral strokes	2 (3.4%)	5 (20%)	.024
Major stroke	1 (1.7%)	4 (16%)	.027
Minor stroke	1 (1.7%)	1 (4%)	NS
Perioperative ipsilateral strokes			
Major and minor	2 (3.4%)	4 (16%)	.064
Major	1 (1.7%)	3 (12%)	.079
Ipsilateral TIA	1 (1.7%)	1 (4%)	NS
Death	0	1 (4%)	NS
Bleeding	1 (1.7%)	1 (4%)	NS
Cranial nerve injury, total	10 (17.2%)	0	.028
Transient	9 (15.5%)	0	.05
Permanent	1 (1.7%)	0	NS

NS, Not significant.

The outcome of the stented group (Group II) was divided into early experience (Group IIA, the first 12 cases) and late experience (Group IIB, the last 13 cases) for learning curve consideration, and each group was compared with the reoperation group. This cutoff of 12 cases was based on the recommendation of the Carotid Revascularization: Endarterectomy versus Stenting Trial group that the interventionalist select 12 to 15 run-in cases of PTA/stenting before formal randomization, and it happened that the last stroke in our PTA/stenting group was the twelfth case.

## RESULTS

The demographic and clinical characteristics were similar in both groups (Table I). There were 25 PTA/stents in 23 patients, two of whom had the same side stented twice. One of these patients had a Palmaz stent initially for an asymptomatic lesion, followed by restenting using a Smart stent for  $\geq 80\%$  asymptomatic restenosis in 24 months. The other patient had a Smart stent initially for TIA symptoms, followed by restenting with another Smart stent for  $\geq 80\%$  asymptomatic restenosis in 12 months. The

indications for intervention were as follows: 46 (79%) versus 18 (72%) for symptomatic restenoses and 12 (21%) versus 7 (28%) for high-grade ( $>80\%$ ) asymptomatic restenoses for Groups I and II, respectively. The mean time from the original CEA to reoperation was 41 months in Group I versus 43 months in Group II. The initial success rate for PTA/stenting was 100%. Palmaz stents were used in our early experience in two patients, Wall stents in 13 patients, and Smart stents in 10 patients.

Table II summarizes the 30-day and all neurologic complications for both groups. Overall, PTA/stenting had higher ipsilateral stroke rates (20%) than reoperations (3.4%,  $P < .05$ ). There were four (16%) 30-day strokes in Group II patients, three of which were major strokes and one of which was a minor stroke, in contrast with two (3.4%, one major and one minor) in Group I ( $P = .064$ ). Three out of four lesions in Group II patients who had early strokes were late recurrent lesions ( $>24$  months after original primary CEA) versus one out of two lesions in Group I. The 30-day stroke rates were comparable between reoperation and PTA/stenting, whether the indication for intervention was symptomatic or asymptomatic (three out of four patients with

**Table III.** 30-day perioperative and all neurologic complications: First 12 cases (Group IIA) versus last 13 cases (Group IIB) of PTA/stenting

<i>Complication</i>	<i>Group IIA (n = 12) (%)</i>	<i>Group IIB (n = 13) (%)</i>	<i>P value</i>
All ipsilateral strokes	5 (41.7)	0	.01
30-day ipsilateral strokes	4 (33.3)	0	.04
Ipsilateral TIA	1 (8.3)	0	NS
Death	1 (8.3)	0	NS
Bleeding*	0	1 (7.7)	NS

\*This patient complicated with leg amputation (see "Results" section).

NS, Not significant.

**Table IV.** Perioperative complications with reoperation (Group I) versus last 13 carotid PTA/stenting cases (Group IIB)

<i>Complication</i>	<i>Reoperation (n = 58) (%)</i>	<i>PTA/stenting, (n = 13) (%)</i>	<i>P value</i>
Ipsilateral stroke	2 (3.4)	0	NS
Major stroke	1 (1.7)	0	NS
Minor stroke	1 (1.7)	0	NS
Ipsilateral TIA	1 (1.7)	0	NS
Death	0	0	NS
Bleeding	1 (1.7)	1 (7.7)	NS
Cranial nerve injury, total	10 (17.2)	0	NS
Transient	9 (15.5)*	0	NS
Permanent	1 (1.7)†	0	NS

\*These include 4 hypoglossal nerves, 3 vagal/brachial nerves (1 superior laryngeal nerve, 1 recurrent laryngeal nerve, and 1 main vagal nerve), and 2 marginal mandibular branches of the facial nerve.

†This was one recurrent laryngeal nerve.

NS, Not significant.

perioperative strokes in the PTA/stenting group were symptomatic versus two out of two in patients with reoperations). The causes of 30-day strokes in Group II patients were embolic in three (two major and one minor stroke) and intracerebral hemorrhage in one. All of these patients had a normal perioperative completion angiogram. All three embolic strokes had poststenting dilatation. One of the patients with cerebral hemorrhage was complicated by multiple organ failure and died perioperatively (this patient had string sign). A fifth patient in Group II (for a late lesion) had an embolic stroke at 32 days postoperatively, which was attributed to ventricular thrombus. The cause of the 30-day strokes in the two patients with reoperations was also embolic with a normal duplex ultrasound scan. There was one major bleeding (noncerebral) in a patient with PTA/stenting. This patient was approached by femoral puncture of the left limb of the aortobifemoral graft that was complicated by postoperative bleeding, necessitating exploration and repair of a tear in the femoral graft; however, immediate postoperative thrombosis developed in this patient and below-knee amputation was eventually required.

Table III summarizes the 30-day and all neurologic complications in Groups IIA and IIB patients. As noted, the four 30-day strokes in Group II occurred in the first 12 cases, and none occurred in the last 13 cases of PTA/stenting ( $P = .04$ ).

Table IV compares the results of the reoperations (Group I) to the last 13 carotid stenting cases (Group IIB). As noted, there were no significant differences in the 30-day stroke or TIA rates or other 30-day complications.

The  $\geq 50\%$  recurrent restenosis rate was higher in Group II than in Group I (6 [24%] versus 0,  $P < .001$ ).

The stroke-free survival rates at 6 months and 1, 2, and 3 years for Group I were 97%, 97%, 94%, and 82%, respectively, versus 79%, 79%, 79%, and 79%, respectively, for Group II ( $P = .059$ ) (Table V, Fig 1). The freedom from recurrent  $\geq 50\%$  restenosis at 6 months and 1, 2, and 3 years were 100%, 100%, 100%, and 100%, respectively, for Group I versus 100%, 94%, 65%, and 44%, respectively, for Group II ( $P < .0001$ ) (Table VI, Fig 2). The stroke-free survival rates and freedom from recurrent  $\geq 50\%$  restenosis rates at 1 year for Groups I and IIB patients were similar (97% and 100% versus 100% and 80%, respectively).

## DISCUSSION

Restenosis of the carotid artery has been detected with increasing frequency because of the increased use of non-invasive testing. Even though the incidence of restenosis has been reported to range from 1% to 36%,<sup>14,15</sup> only 1% to 8% of all patients undergoing CEA will develop hemodynamically significant restenosis. Early restenoses are

**Table V.** Life table analysis of time to stroke or death for reoperation (Group I) and carotid PTA/stenting (Group II) patients

<i>Interval (mo)</i>	<i>No. at risk at start</i>	<i>No. failed</i>	<i>Stroke-free survival rate (%)</i>	<i>Standard error (%)</i>
Group I				
Entry	58	0	100	0
1	56	2	98	1.7
6	50	2	97	2.4
12	45	0	97	2.4
24	27	1	94	3.6
36	12	2	82	8.4
42	4	1	73	11.4
Group II				
Entry	25	0	100	0
1	21	4	87	3.9
6	14	5	79	8.5
12	11	0	79	8.5
24	4	0	79	8.5
36	1	0	79	8.5
42	1	0	79	8.5

**Table VI.** Life table analysis of time to recurrent  $\geq 50\%$  restenosis for reoperation (Group I) and carotid PTA/stenting (Group II) patients

<i>Interval (mo)</i>	<i>No. at risk at start</i>	<i><math>\geq 50\%</math> restenosis</i>	<i>Recurrent stenosis-free rates (%)</i>	<i>Standard error (%)</i>
Group I				
Entry	58	0	100	0
1	58	0	100	0
6	52	0	100	0
12	46	0	100	0
24	28	0	100	0
36	11	0	100	0
42	3	0	100	0
Group II				
Entry	25	0	100	0
1	24	0	100	0
6	19	0	100	0
12	15	2	94	5.7
24	6	3	65	12.9
36	2	1	44	19.7
42	1	0	44	19.7

mostly a consequence of myointimal hyperplasia, and those occurring after 2 years are generally associated with atherosclerosis.<sup>7,16,17</sup>

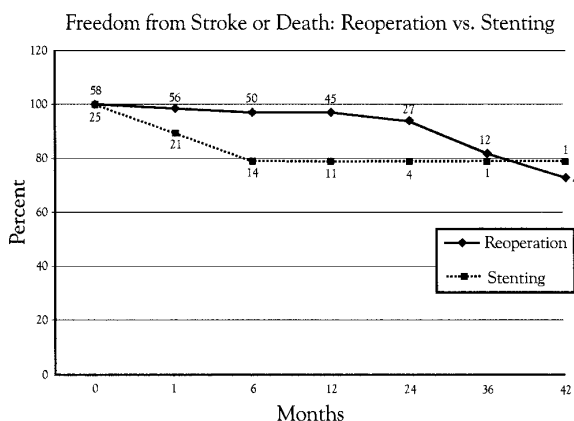
There is a general consensus among surgeons that reoperation for significant symptomatic restenosis is indicated, whereas the indication for reoperation for asymptomatic restenosis is somewhat controversial.<sup>4,5,8</sup> Reoperation is generally believed to be more difficult than primary CEA, largely because of the dense scarring surrounding the carotid artery and the difficulty in obtaining tissue cleavage planes. Higher morbidity and mortality rates (8%-20%) after reoperation have been documented,<sup>6,7,9,18</sup> although some recent studies suggest that the risk has improved.<sup>15,19-21</sup> O'Donnell et al<sup>8</sup> also reported on the results from a meta-analysis of six series that showed a 4.2% stroke rate and a 1% mortality rate, for a combined rate of 5.2%. He also indi-

cated that the incidence of cranial nerve injuries in patients with reoperation surgery averaged 8.5% in these series versus 16% in his series.<sup>8</sup>

Recently, Hill et al<sup>21</sup> reported lower 30-day stroke and death rates for reoperation (0%) compared with primary CEA (1.1%) in a group of 390 CEAs (40 reoperations and 350 primary CEAs).

Carotid PTA/stenting is increasing in popularity and has been advocated by some investigators as an alternative to reoperation for carotid restenosis.<sup>9-13</sup> The safety and efficacy of this approach is currently being investigated. The Carotid Revascularization: Endarterectomy versus Stenting Trial,<sup>22</sup> which is currently underway, is comparing the results of operative and PTA/stenting for primary carotid stenosis.

Angioplasty/stenting has been justified for the treatment of restenosis on the basis that this procedure is sim-

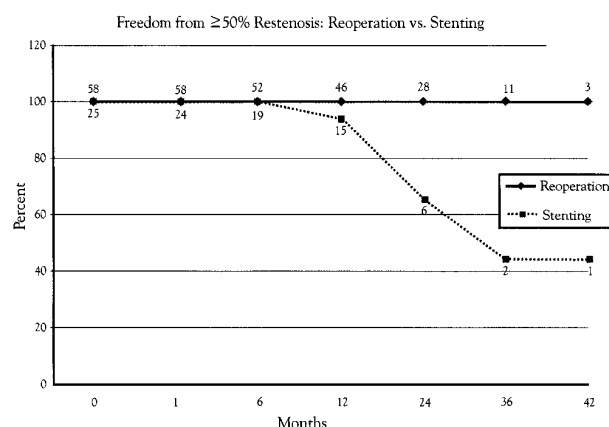


**Fig 1.** Kaplan-Meier curves for stroke-free survival rates for Groups I and II.

ple to perform and the pathology of early restenosis is myointimal hyperplasia, rendering these patients amenable to PTA. It is generally believed that such hyperplastic lesions are not likely to embolize.

Yadav et al<sup>11</sup> reported on their experience with 25 CEAs (22 patients) treated with PTA and stenting for carotid restenosis and found a 4% perioperative stroke rate with no secondary restenoses at 6-month follow-up. Lanzino et al<sup>23</sup> reported on their experience with 25 PTA/stentings on 21 patients for carotid restenosis with no major periprocedural neurologic deficits or deaths. There was one periprocedural TIA, and a pseudoaneurysm of the femoral artery developed in another patient at the access site, which required surgical repair. In 16 patients who underwent at least 6 months of follow-up review, no neurologic events ipsilateral to the treated artery had occurred after a mean follow-up period of 27 months. Significant restenosis ( $\geq 50\%$ ) was observed in only one of the vessels treated. The authors concluded that PTA/stenting for carotid restenosis is both technically feasible and safe and has a satisfactory midterm patency and should be considered a valuable alternative to reoperation in patients with carotid restenosis.

Bergeron et al<sup>10</sup> reported on the results of PTA/stenting for carotid restenosis in 15 patients (11 had PTA alone and 4 had stenting). Two postdilatation complications (dissection and acute occlusion) required prompt stenting; one common carotid artery was stented for postdilatation residual stenosis, and one recurrent lesion was stented 6 months after the initial angioplasty. They also reported 1 stroke, 1 silent cerebral infarction, and 3 TIAs (33% neurologic complication rate), and one patient died 3 days postoperatively from hyperperfusion syndrome. Long-term follow-up in two stent patients showed no restenosis at 18 and 48 months. The 11 PTA patients, likewise, have not demonstrated restenosis. They concluded that PTA alone appeared to be too risky for treating restenosis. However, stents may offer a safer alternative, particularly when implanted primarily.



**Fig 2.** Kaplan-Meier curves for freedom from recurrent  $\geq 50\%$  restenosis rates for Groups I and II.

In a recent multicenter study, New et al<sup>24</sup> reported on the safety, efficacy, and durability of carotid stenting for restenosis after CEA. Three hundred fifty-eight arteries (338 patients) had carotid PTA/stenting. The average duration from the CEA to carotid stenting was 5.5 years. Sixty-one percent of these patients were asymptomatic. The 30-day stroke and death rate was 3.7%. The minor stroke rate was 1.7%, the major nonfatal stroke rate was 0.8%, and the fatal stroke rate was 0.3%. There was one (0.3%) fatal and one (0.3%) nonfatal stroke during the follow-up period. Overall, the 3-year rate of freedom from all fatal and nonfatal strokes was  $96\% \pm 1\%$  ( $\pm$  SE). They concluded that carotid artery stenting can be performed in patients with restenosis with 30-day perioperative complication rates, comparable with most published series on reoperation. They also indicated that the technique was durable and efficacious.

None of these reports compared reoperation to PTA/stenting for carotid restenosis in the same institution. To our knowledge, there has only been one comparative study between reoperation and carotid PTA/stenting for carotid restenosis.<sup>13</sup>

Hobson et al<sup>13</sup> reported comparable early results for reoperation and PTA/stenting for patients with carotid restenosis. During an 8-year period, early restenosis (18 months after primary CEA) was managed with reoperation in 16 cases and with carotid PTA/stenting in 15 others. There were no 30-day strokes or deaths in either group. Duplex ultrasound scan results in the PTA/stenting group revealed no restenosis or stent occlusion with a mean follow-up of 7 months.

A direct comparison of CEA versus stenting is difficult in this retrospective study because many patients who underwent carotid stenting were considered nonsurgical candidates because of the high cervical location of the lesion, previous cranial nerve injury, or severe comorbidities. However, we attempted to create as much uniformity as possible in our two study groups to draw an accurate

comparison. Both groups had similar clinical and demographic characteristics, and only one surgeon's and one vascular medicine interventionalist's experiences were analyzed. Overall, stenting had higher stroke rates than reoperation when all patients with stenting were included (20% versus 3.4%,  $P < .05$ ). However, when the outcome of the stented group was subdivided into early and late experience for learning curve consideration, the stenting group had a major stroke rate similar to the reoperation group (0% versus 1.7%). It should be noted that the number of arteries in Group IIA and IIB were 12 and 13, respectively, which carries with it a substantial chance of a type II statistical error because of the small sample size. The early high stroke rates with carotid stenting were most likely related to patient selection and learning curve. Changes in anticoagulation, avoiding subtotal "string sign" lesions with baseline slow flow, and poststent dilatation practice changes have positively influenced the outcome in Group IIB. Al-Mubarak et al<sup>25</sup> reported that patients who were more than 80 years old or who had tortuosity of the aortic arch or carotid artery have a greater likelihood of embolic event during carotid PTA/stenting. None of our PTA/stenting patients had this pathology, and only one patient was more than 80 years old. As expected, we found an increase in the number of transient cranial nerve injuries (17%) in the reoperation group; however, only 1.7% had a permanent cranial nerve injury. As noted in Table V, the stroke-free survival rate at 6 months and 1, 2, and 3 years for reoperation were somewhat better than for Group II (stenting); however, this was not statistically significant ( $P = .059$ ), which may be explained by the small sampling size. The freedom from  $\geq 50\%$  recurrent restenosis rates at 6 months and 1, 2, and 3 years were 100%, 100%, 100%, and 100%, respectively, for reoperation versus 100%, 94%, 65%, and 44%, respectively, for the stented group ( $P = .0001$ ).

In conclusion, carotid PTA/stenting has a 30-day stroke rate similar to that of reoperation for carotid restenosis once experience is established. However, PTA/stenting has a higher incidence of recurrent restenosis than reoperation, which may be associated with cranial nerve injury. Therefore, PTA/stenting can be an alternative for reoperation, particularly in marginal surgical risk patients. In the future, carotid protection devices may further reduce the risk of periprocedural embolic events, and stents coated with drugs may reduce restenosis; however, at this stage, the exact role of transcatheter intervention in the management of carotid artery restenosis remains to be seen.

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## DISCUSSION

**Dr Michael B. Silva** (Lubbock, Tex). I would like to congratulate Dr AbuRahma on an excellent presentation and his group for the careful examination of their experience in initiating a program in carotid angioplasty and stenting. I have a few questions.

With the average time to restenosis in both groups approximately three and a half years after initial carotid endarterectomy, the probability is that these stenoses were recurrent atherosclerotic lesions rather than myointimal hyperplastic lesions. Did you look at angiographic or duplex characteristics which might better...

[end of cassette]

... your insights as to the potential for reducing risks to an appropriate level which would justify more widespread adoption of these practices by the surgeons in this room.

Thank you very much, Ali, for providing me with the manuscript well in advance and thank you to the society for the privilege of the floor.

**Dr Ali F. AbuRahma.** I appreciate your comments. In regards to recurrent stenosis in these cases, they were as you suggested. Most of the perioperative strokes occurred in patients with late recurrent stenosis (>24 months). Actually, 3 out of 4 patients who had early strokes in the PTA/stenting group were related to late recurrent stenosis, and 1 out of 2 patients with early stroke in the reoperation group were also related to recurrent stenosis.

The type of stenting used included two Palmaz stents in our early experience, followed by 11 Wall stents, and the last 12 cases were Smart stents.

It is true that the recurrent stenoses in the PTA group were much higher, but most of these were asymptomatic.

Finally, in regard to the experience of the operator (MB), the peripheral interventionalist had performed over several thousand various peripheral vascular interventions, including aortoiliac, femoropopliteal, renal/subclavian/brachiocephalic. At least 40 of these were carotid PTA/stenting. He has extensive experience in peripheral vascular intervention.

**Dr Nicos Labropoulos** (Maywood, Ill). I just want to make a general comment. About a year ago, the University of Chicago asked me to give a talk on recurrent carotid stenosis. To my surprise, I looked at all the literature and I found out that the inci-

dence of events in people who have recurrent carotid stenosis is very low. If your meta-analysis shows a 4.2% event rate after the procedure, should we do this operation at all? Your question might be that recurrent carotid stenosis might lead to occlusion. Unfortunately, in the prospective fashion, nobody has studied the natural history of recurrent carotid stenosis. If we look at the data on atherosclerosis, there is only one paper from Moneta showing that if you have an atherosclerotic primary lesion, the occlusion rate is 11% at 3 years. However, there are no such data for recurrent carotid stenosis. With such a high incidence of events, it is really questionable if we should do anything about these patients at all.

**Dr AbuRahma.** I would like to point out, as I presented earlier, that the indication for the reoperation PTA/stenting was primarily for symptomatic patients (TIA/stroke), specifically 79% in the reoperation group and 72% in the PTA/stenting group. The remaining indications were for  $\geq 80\%$  asymptomatic stenosis.

**Dr Alan Lumsden** (Atlanta, Ga). There is clearly a huge difference between your early and your late experience. Part of that is where you draw the line and say this is the definition of early and this is the definition of late. If you look at your last major event and say everything after that which is incident-free is late, it is going to be pretty impressive data when you look at it. What was the duration of your early experience versus the later experience?

**Dr AbuRahma.** That is a good point. The time frame for the PTA/stenting were: the first 12 cases were done over the first 26 months and the remaining 13 were done over the remaining 18 or 19 months.

**Dr John Ricotta** (Stony Brook, NY). Ali, let me just ask you one question. There had been some concern about manipulation and recurrent stenosis in patients who have patches in terms of higher event rate. Do you know how many of them had patches and how many did not?

**Dr AbuRahma.** That is a good point. Actually, all of the stenting were primary closures except two patients with patches, so it would be difficult to tell you whether patching had anything to do with it or not.

## IMAGES AND REFLECTIONS

A new section in the *Journal of Vascular Surgery*, Images and Reflections, gives authors the opportunity for reflection by submitting creative writing (prose or poetry), photographs, artwork, and unique aspects of medical history.

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